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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/088,807 | 07/29/2002 | James Duncan Morrison | 9013-46 | 2452 |

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,807

Applicant(s)

MORRISON ET AL.

Examiner

Maury Audet

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-23,35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 24-34,37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION**Election/Restriction**

Applicant's election of Group II, claim 2, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Along with the above, Applicant filed an amendment adding new claims 24-42. Claims 2, 24-34, and 37-42 are examined on the merits. Claims 1, 3-23, and 35-36, drawn to a nonelected invention(s) or species, are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Examination of the Claims

Please note that the claims have been examined over the art only in so far as they read upon the elected invention (i.e. insulin conjugated to a bile acid/salt).

Rejections***Claim Rejections - 35 USC § 103***

Claims 2, 24-34, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swaan et al. (Bioconj. Chem, 1997, pp. 520-525) in view of Balschmidt et al. (US 5053389), Fukuda (EP 0689052 A2), Kidron et al. (US 4579730), and Yoo (6251428 B1)).

Swaan et al. teach the amide of a bile acid/salt of instant formula (II) conjugated to various therapeutic small molecular weight peptides through a carboxyl (CO-) group, so as to enhance oral absorption thereof, in a pharmaceutical composition. Swann et al. does not expressly teach the use of insulin conjugated to the carboxy group (CO-) of a bile acid.

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However, please note that insulin is notoriously well recognized in the art as being a small molecular weight therapeutic peptide.

Balschmidt et al. teach the amide of a bile acid/salt of formula (II) in a composition with insulin, for enhanced oral absorption of insulin, in a pharmaceutical composition, for the treatment of a subject, along with a method of making a pharmaceutical composition thereof (see entire document).

Fukuda teach the amide of a bile acid/salt of formula (II) in a composition with insulin, for enhanced oral absorption of insulin, in a pharmaceutical composition, for the treatment of a subject, along with a method of making a pharmaceutical composition thereof (see entire document).

Kidron et al. teach the amide of a bile acid/salt of formula (II) in a composition with insulin, for enhanced oral absorption of insulin, in a pharmaceutical composition, for the treatment of a subject, along with a method of making a pharmaceutical composition thereof (see entire document).

Yoo teaches the amide of a bile acid/salt of formula (II) in a composition with insulin, for enhanced oral absorption of insulin, in a pharmaceutical composition, for the treatment of a subject, along with a method of making a pharmaceutical composition thereof (see entire document).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the insulin of Balschmidt et al., Fukuda, and Kidron et al., and/or Yoo, in a conjugation to bile acid at the CO-group as disclosed in Swann et al., so as to

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advantageously provide even greater tissue absorption of the insulin, based upon the beneficial teachings therein.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

June 26, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER